

SEP 11 2008

510(k) Summary
ADVIA Centaur® Cyclosporine Assay

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K071455

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Submitter: Siemens Healthcare Diagnostics
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Tarrytown, New York 10591-5097

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Date of Preparation: August 19, 2008

2. Device Name / Classification

Common Name: Cyclosporine
Trade Name: ADVIA Centaur® Cyclosporine Assay
ADVIA Centaur® Cyclosporine Calibrator
FDA Classification: Sec. 862.1235, 862.3200
Cyclosporine Test system – Class II Special controls
Clinical Toxicology Calibrator

3. Identification of the Predicate Devices

Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood assay, P890025

4. Device Description

The ADVIA Centaur® Cyclosporine assay is a competitive immunoassay using direct chemiluminescent technology. Cyclosporine in the patient sample competes with acridinium ester-labeled cyclosporine in the Lite Reagent for a limited amount of biotin-labeled monoclonal mouse anti-cyclosporine antibody. Biotin-labeled anti-cyclosporine binds to streptavidin that is covalently coupled to paramagnetic particles in the

Solid Phase. In the ADVIA Centaur® Cyclosporine assay the sample is manually pretreated to lyse the cells and solubilize the cyclosporine.

An inverse relationship exists between the amount of cyclosporine present in the patient sample and the amount of relative light units (RLUs) detected by the system.

5. Device Intended Use

The ADVIA Centaur® Cyclosporine assay is an *in vitro* diagnostic immunoassay for the quantitative determination of cyclosporine in human whole blood using the ADVIA Centaur systems. This assay is intended for use as an aid in the management of cyclosporine therapy in kidney, heart, and liver transplant patients.

The ADVIA Centaur® Cyclosporine Calibrator is for *in vitro* diagnostic use in the calibration of the Cyclosporine assay on the ADVIA Centaur® system.

6. Comparison to Predicate Devices

The ADVIA Centaur® Cyclosporine assay is substantially equivalent to Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood assay in that:

- Both are immunoassays intended for use in the quantitative measurement of cyclosporine in human whole blood.
- Both assays use mouse monoclonal antibody
- Both assays require pretreatment of patient samples.

The ADVIA Centaur® Cyclosporine assay and Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood assay differ in that:

- The ADVIA Centaur® Cyclosporine assay does not require whole blood precipitation reagent before testing.
- The ADVIA Centaur® Cyclosporine assay does not require pretreatment of calibrators.

Comparison Information

Method comparison studies were conducted at three external sites comparing the ADVIA Centaur® Cyclosporine assay against two predicates:

- Tandem Mass Spectrometry, and
- The Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood assay.

Samples from three transplant patient groups (heart, kidney and liver) were used in the studies. The data from all three sites were analyzed by Deming regression.

Comparative Method	Transplant Type	Number of Patient Samples	Deming Regression		Correlation Coefficient
			Slope	Intercept	
Tandem-MS	kidney	108	1.11	-8	0.962
	liver	75	1.04	-5	0.967
	heart	67	0.89	20	0.966
	all	250	1.03	-1	0.963

Comparative Method	Site	Number of Patient Samples	Deming Regression		Correlation Coefficient
			Slope	Intercept	
Tandem-MS	site 1	97	0.88	13	0.979
	site 2	105	0.85	23	0.988
	site 3	48	1.11	46	0.965
	all	250	0.94	19	0.960
Abbott TDx	site 1	97	0.78	8	0.977
	site 2	97	0.68	-3	0.988
	site 3	48	0.71	22	0.977
	all	242	0.72	6	0.977
Abbott AxSym	site 1	219	0.68	18	0.960

Comparative Method	Site	Number of Patient Samples	Deming Regression		Correlation Coefficient
			Slope	Intercept	
Tandem-MS	trough	182	1.02	8	0.909
	peak	68	1.15	-104	0.898
	all	250	1.03	-1	0.963

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

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Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K071455

Device Name: ADVIA Centaur Cyclosporine Assay and Calibrators

Indication For Use: The ADVIA Centaur Cyclosporine assay is an *in vitro* diagnostic immunoassay for the quantitative determination of cyclosporine in human whole blood using the ADVIA Centaur systems. This assay is intended for use as an aid in the management of cyclosporine therapy in kidney, heart, and liver transplant patients.

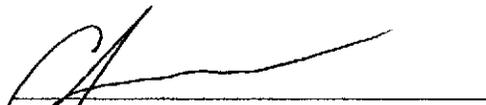
Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K071455